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PTO/SB/21 (09-04)

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FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

520

Application Number

10/750,475

Filing Date

12-31-2003

First Named Inventor

Alavattam et al.

Art Unit

1653

Examiner Name

Gargi, Roy

Attorney Docket Number

13447

ENCLOSURES (Check all that apply)

Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Reply to Missing Parts/
Incomplete ApplicationReply to Missing Parts
under 37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

Petition to Convert to a
Provisional ApplicationPower of Attorney, Revocation
Change of Correspondence Address

Terminal Disclaimer



Request for Refund



CD, Number of CD(s) _____

☐ Landscape Table on CD

Remarks



After Allowance Communication to TC

Appeal Communication to Board
of Appeals and InterferencesAppeal Communication to TC
(Appeal Notice, Brief, Reply Brief)

Proprietary Information



Status Letter

Other Enclosure(s) (please identify
below):IDS Letter; PTO-2038; Return Receipt Post
Card; Copies of 1973 and 1975 patents;
Copies of Non-patent Literature ;

Copies of foreign art

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Battelle Memorial Institute

Signature

Printed name

Klaus H. Wiesmann

Date

01-27-2006

Reg. No.

30,437

CERTIFICATE OF TRANSMISSION/MAILING

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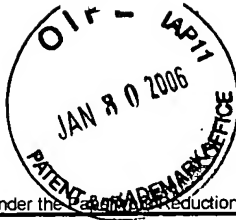
Judy Readman

Date

01-27-2006

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/750,475
Filing Date	12-31-2003
First Named Inventor	Alavattam et al.
Art Unit	1653
Examiner Name	Gargi, Roy
Attorney Docket Number	13447

Sheet 1 of 6

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	US- 3,773,919	11-20-1973	Boswell et al.	
	A2	US- 3,887,699	06-03-1975	Yolles	
	A3	US- 4,293,339	10-06-1981	Supcoe et al.	
	A4	US- 4,675,189	06-23-1987	Kent et al.	
	A5	US- 5,700,486	12-23-1997	Canal et al.	
	A6	US- 5,759,583	06-02-1998	Iwamoto et al.	
	A7	US- 5,981,719	11-09-1999	Woiszwilllo et al.	
	A8	US- 5,985,309	11-16-1999	Edwards et al.	
	A9	US- 6,120,787	09-19-2000	Gustafsson et al.	
	A10	US- 6,238,705	05-29-2001	Liu et al.	
	A11	US- 6,294,202	09-25-2001	Burns et al.	
	A12	US- 6,391,296	05-21-2002	Okano et al.	
	A13	US- 6,896,894	05-24-2005	Brody et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	A14	EP 0 950 663 A1	10-20-1999	Okano et al.		
	A15	WO 02/28370 A1	04-11-2002	Jonsson et al.		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/750,475		
		Filing Date	12-31-2003		
		First Named Inventor	Alavattam et al.		
		Art Unit	1653		
		Examiner Name	Gargi, Roy		
Sheet	2	of	6	Attorney Docket Number	13447

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	AUSTIN et al.; The Controlled Release of Leukaemia Inhibitory Factor (LIF) From Aliginate Gels; Pro Intern Symp Control Rel Bioact Mater; 23; 1996; pp 739-740	
	B2	BRANNON-PEPPEAS et al.; Polyactic and Polyglycolic Acids as Drug Delivery Carriers; Handbook of Pharmaceutical Release Tech; 2000; pp 99-130; Marcel Dekker; New York	
	B3	BURGESS et al.; Glucuronidase Activity Following Complex Coacervation & Spray Drying Micoencapsulation; J. Microencapsulation; 1998; Vol 15; No. 5; pp. 569-579	
	B4	BURKE, PAUL; Controlled Release Protein Therapeutics: Effects of Process & Formulation on Stability; Handbook of Pharmaceutical Controlled Release Tech; 2000; pp. 661-692;	
	B5	CHANG, THOMAS; Biodegradable Semipermeable Microcapsules Containing Enzymes Hormones Vaccines & Other Biologicals; J of Bioengineering; 1976; Vol 1; pp 25-32	
	B6	CHEN et al. Polysaccharide Hydrogels for Protein Drug Delivery; Carbohydrate Polymers 28; 1995; pp 69-76; Elsevier; Great Britain	
	B7	CLELAND et al.; Stable Formulations of Recombinant Human Growth Hormone & Interferon- for Microencapsulation in Biodegradable Microspheres; Pharmaceutical Research; Vol 13; No 10; 1996; pp. 1464-1475	
	B8	CROTTS et al. Protein Delivery From Poly(lactic-co-glycolic acid) Biodegradable Microspheres: Release Kinetics & Stability Issues; J Microencapsulation 1998; 15; 6; pp 699-713	
	B9	DE ROSA et al; Influence of Co-encapsulation of Different Non-Ionic Surfactants on the Properties of PLGA Insulin-loaded Microspheres; J Controlled Release 69 2000 pp 283-295	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	3	of	6	Application Number	10/750,475
				Filing Date	12-31-2003
				First Named Inventor	Alavattam et al.
				Art Unit	1653
				Examiner Name	Gargi, Roy
				Attorney Docket Number	13447

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	GOMBOTZ et al.; Protein Release From Alginate Matrices; Advanced Drug Delivery Reviews; 31; 1998; pp 267-285; Elsevier	
	C2	HUANG et al.; On The Importance & Mechanisms of Burst Release in Matrix-controlled Drug Delivery Systems; J of Controlled Release; 73; 2001; pp 121-136; Elsevier	
	C3	JAIN et al.; Controlled Drug Delivery by Biodegradable Poly(Ester) Devices: Different Preparative Approaches; Drug Development & Industrial Pharmacy; 1998; Vol 24; pp 703-727	
	C4	JIANG et al.; Stabilization & Controlled Release of Bovine Serum Albumin Encapsulated in Poly(D, L-lactide) and Poly(ethylene glycol) Microsphere Blends; Pharmaceutical Research; Vol 18; 6; 2001; pp 878-885	
	C5	JOHANSEN et al; Improving Stability & Release Kinetics of Microencapsulated Tetanus Toxoid by Co-Encapsulation of Additives; Pharmaceutical Research Vol 15; 7 1998 pp 1103-1110	
	C6	LEE et al.; Double Walled Microparticles For HBV Single Shot Vaccine; Proceed Intern Symp Control Rel Bioact Mater; 23; 1996; pp 333-334; #4103; Controlled Release Soc	
	C7	LI et al.; A Novel Biodegradable System Based on Gelatin Nanoparticles and Poly(lactic-co-glycolic acid) Microspheres for Protein and Peptide Drug Delivery; J Pharmaceutical Sciences; Vol 86; No 8; August, 1997; pp 891-895	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/750,475
		Filing Date	12-31-2003
		First Named Inventor	Alavattam et al.
		Art Unit	1653
		Examiner Name	Gargi, Roy
Sheet 4	of 6	Attorney Docket Number	13447

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	D1	MORLOCK et al.; Erythropoietin Loaded Microspheres Prepared From Biodegradable LPLG-POE-LPLG Triblock Copolymers: Protein Stabilization and In-vitro Release Properties;	
		J of Controlled Release; 56; 1998; pp 105-115; Elsevier	
	D2	PARK et al.; Poly(L-lactic acid) Pluronic Blends: Characterization of Phase Separation Behavior, Degradation and Morphology and Use as Protein-Releasing Matrices;	
		Macromolecules; 1992; 25; pp 116-122; American Chemical Society	
	D3	PATIL et al.; Water-Based Microsphere Delivery System for Proteins; J of Pharmaceutical Sciences; Vol 89; No 1; January 2000; pp 9-15	
	D4	PEAN et al.; Why Does PEG 400 Co-Encapsulation Improve NGF Stability & Release From PLGA Biodegradable Microspheres; Pharmaceutical Research; Vol 16; No 8; 1999; pp 1294-1299	
	D5	PROKOP et al.; Water Soluble Polymers ^{for} Immunoisolation II: Evaluation of Multicomponent Microencapsulation Systems; Advances in Polymer Science; Vol 136; pp 53-73; 1998	
	D6	PUTNEY et al.; Encapsulation of Proteins for Improved ^{et} Delivery; Current Opinion In Chemical Biology; 1998; 2 pp 548-552	
	D7	ROSKOS et al.; Degradable Controlled Release Systems Useful for Protein Delivery; Protein Delivery: Physical Systems, Sanders & Hendren eds.; Plenum Press; NY; pp 45-92; 1997	

Examiner Signature	Date Considered
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/750,475
				Filing Date	12-31-2003
				First Named Inventor	Alavattam et al.
				Art Unit	1653
				Examiner Name	Gargi, Roy
Sheet	5	of	6	Attorney Docket Number	13447

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	E1	SANCHEZ et al.; Formulation Strategies for Stabilization of Tetanus Toxoid in Poly (lactide-co-glycolide) Microspheres; Inter J of Pharmaceutics; 185; 1999 pp 255-266; Elsevier	
	E2	SANDOR et al.; Effect of Protein Molecular Weight on Release From Micro-Sized PLGA Microspheres; J of Controlled Release; 76; 2001; pp 297-311; Elsevier	
	E3	SEZER et al.; Release Characteristics of Chitosan Treated Alginate Beads: I. Sustained Release of a Macromolecular Drug From Chitosan Treated Alginate Beads;	
		J Microencapsulation; 1999; Vol 16; No 2; pp 195-203	
	E4	Van DE WEERT et al.; Protein Instability in Poly(Lactic-co-Glycolic Acid) Microparticles; Pharmaceutical Research; Vol 17; No 10; 2000; pp 1159-1167	
	E5	WAKEMAN et al.; COncentration and Fractionation of Polyvinyl Alcohol-anionic Surfactant Stabilised Latex Dispersions by Microfiltration; J Membrane Science; 106; 1995 pp 57-65	
	E6	WANG et al.; A heterogenously Structured Composite Based on Poly(lactic-co-glycolic acid) Microspheres and Poly (vinyl alcohol) Hydrogel Nanoparticles for Long-Term Protein	
		Drug Delivery; Pharmaceutical Research; Vol 16; No 9; 1999; pp 1430-1435	
	E7	WANG et al.; A Novel Approach to Stabilization of Protein Drugs in Poly(lactic-co-glycolic acid) microspheres Using Agarose Hydrogel; International Journal of Pharmaceutics;	
		166; 1998; pp 1-14	

Examiner Signature	Date Considered
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		Application Number	10/750,475
		Filing Date	12-31-2003
		First Named Inventor	Alavattam et al.
		Art Unit	1653
		Examiner Name	Gargi, Roy
Sheet 6	of 6	Attorney Docket Number	13447

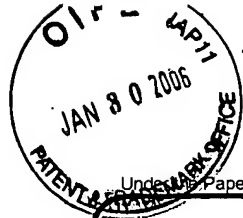
NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	F1	WHEATLEY et al.; Coated Alginate Microspheres: Factors Influencing the Controlled Delivery of Macromolecules; J of Applied Polymer Science; Vol 43; pp 2123-2135; 1991	
	F2	WOO et al.; Preparation and Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for Protein Delivery; Pharmaceutical Research; Vol 18; No. 11; November, 1992; pp 1600-1606	
	F3	ZHU et al.; Stabilization of Proteins Encapsulated in Injectable Poly (lactide-co-glycolide); Nature Biotechnology; Vol 18; January, 2000; pp 52-57	

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PTO/SB/17 (01-06)

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

Application Number	10/750,475
Filing Date	12-31-2003
First Named Inventor	Alavattam et al.
Examiner Name	Gargi, Roy
Art Unit	1653
Attorney Docket No.	13447

METHOD OF PAYMENT (check all that apply)☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☐ Deposit Account Deposit Account Number: _____ Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayments

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FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
50	25
200	100
360	180

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____ - 20 or HP = _____ x _____ = _____			

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____ - 3 or HP = _____ x _____ = _____			

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): JDS

180.00

SUBMITTED BY

Signature	<i>Klaus H. Wiesmann</i>	Registration No. (Attorney/Agent)	30,437	Telephone	614-424-6589
Name (Print/Type)	Klaus H. Wiesmann			Date	01-27-2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

Attorney Docket No. 13447

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Alavattam et al.

Serial No.: 10/750,475

Art Unit: 1653

Filed: December 31, 2003

Examiner: Gargi, Roy

For: Biodegradable Microparticles That Stabilize and Control the Release of Proteins

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

1. Preliminary Statement

Applicants submit herewith patents, publications, or other information, of which they are aware that they believe may be material, as defined in 37 CFR § 1.56(b), to the examination of this application, and in respect of which, there may be a duty to disclose in accordance with 37 CFR § 1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 CFR §1.56(b), the filing of this Information Disclosure Statement is not intended, pursuant to 37 CFR §1.97(h), to constitute an admission that any patent, publication, or other information referred to is, or is considered to be, material to the patentability of this invention. Further, pursuant to 37 CFR §1.97(g), the filing of this Information Disclosure Statement should not be construed as a statement that a search has been made or that no other material information exists. The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

2. Transmitted herewith and forming a part of this Information Disclosure Statement are forms PTO/SB/08A (1 sheet) and PTO/SB/08B (5 sheets) on which is listed all cited items of information.

The following references are cited:

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3. Enclosed herewith is the fee of \$180 for submission of this Information Disclosure Statement as specified in 37 CFR §1.17(p).

The person making this statement is the practitioner who signs below on the basis of the information in the practitioner's file.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Klaus H. Wiesmann', with a long horizontal flourish extending to the right.

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